

U.S. Patent Application Serial No. 10/671,704
Reply to Office Action dated September 12, 2006

Remarks:

Applicant has read and considered the Office Action dated September 12, 2006 and the references cited therein. Claims 1, 6 and 7 have been amended, claims 1-17 are currently pending.

Claim Rejections 35 U.S.C. § 102 Basis of the Rejection:

In the Office Action, the present invention is rejected as being anticipated by ABREU (US Patent No. 6,544,193). This rejection is respectfully traversed for the following reasons.

Claims 1 to 6 (as amended) in the present application refer to an apparatus where the direct magnetic field is not only used in (a) combination with an optical field but also, (b) simultaneously with an optical field. The electromagnetic, optical excitation (used to excite the photosensitizer drug to various electronic states) must NECESSARILY and concurrently be combined with an independent, external magnetic field at the position of the sample throughout the entirety of the measurement (claim 1). The optical excitation alone, or the magnetic field alone, or used sequentially, cannot produce the desired experimental conditions of the present application (i.e. the optical and the DIRECT magnetic excitation of the photosensitizer cannot operate in isolation of one another, and the totality of the system is necessarily needed to produce a specific chemical state of the drug). See page 2, Summary of the Invention. Thus the optical excitation and the magnetic-chemical perturbation of the sample (by the magnetic field itself) are inextricably linked in the present invention. This is not the case in ABREU's contact device where the force from the converted magnetic field is applied (to move an element and subsequently flatten a surface) and the optical measurement of the surface is made. In the present invention, the magnetic field, along with the optical field must be both simultaneously applied for the chemical change.

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The purpose of the magnet in ABREU's patent (as described at column 73 line 45-55) is to use to effect a physical displacement (an actuation) of a magnetic element to physically flatten a surface in a "piston like manner" (clearly described in SUMMARY OF INVENTION column 12, lines 17-30). As further described in ABREU's column 73 lines 50-59, the change in magnetic field strength allows for a change in the intensity of the physical actuation. For a completely different purpose, the present invention uses the actual magnetic field (not a conversion to a physical force) to perturb a CHEMICAL reaction in a photosensitizer drug, which has an optical consequence in an optical domain and thus the result is measured optically. To summarize, in the present invention, the magnetic field perturbs a chemical reaction. In ABREU, the magnetic field causes only a physical displacement.

In the present invention, the varying magnetic field is used to specifically select the photochemical reaction pathway (of the photosensitizer) in a unique range of weak magnetic fields (around 0.01 Tesla). Furthermore, the present invention emphasizes in the background description of the invention (beginning on page 4, line 1) that it is **WEAK** magnetic fields (around 0.01 Tesla) which can access the desired and relevant chemical reaction of the drug which is optically accessible by the described apparatus. On the other hand, ABREU uses a varying field (around 0.5 T) to control the intensity of the physical force applied against a surface (cornea) and NOT to produce a chemical or to select the reaction pathway and teaches away from the present invention. Therefore, whereas the present invention uses the magnetic field directly and concurrently with the optical field, ABREU converts the magnetic field to a force. The force causes a flatness, which is measured optically, (i.e. each is sequential – the magnet produces a physical force, and the response is measured optically). Applicant asserts that claims 1-6 patentably distinguish over ABREU.

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Claim Rejections 35 U.S.C. 103

Basis of the Rejection:

Claims 1, 3, and 5-17 are rejected as being obvious over CHANCE, in light of LILGE.

Applicant agrees with the Examiner that some instrumental components in the apparatus of CHANCE, in light of LILGE, are common to the present invention (i.e. magnets in an optical system), and that CHANCE's apparatus could be applicable to monitoring PDT effects on bulk tissue properties. However, the use of the magnetic field according to the present invention has a completely different role/function and result which is NOT obvious from any combination of CHANCE and LILGE, and in view of the amended claims. Magnets, spectrophotometers, fiber-optics analyzers and processors can be common components to many instruments, but how they are utilized, operated, how they interact, and their intended medium of measure, define their specific function and purpose.

The apparatus of the present invention is based on the following fundamental concept: the magnetic field governs the photochemical reaction of the photosensitizer (PDT drug). The manner as well as the intention in which the magnetic field is used and manipulated as recited in claim 1 is fundamentally unique and original in that it is specifically used to induce a chemical change in the state of a photoreactive specie (PDT) state by coupling the magnetic field simultaneously to an optical excitation. The result is that reaction dynamics and mechanisms of the photoreactive species are altered, and hence the drug treatment efficacy, which is measured optically. The manner, as well as the intention, of CHANCE's magnet is as a tool for tissue stimulation, for the overall purpose of tracking its activity through an optical imaging module (i.e. invention of an optical tomography system, based on optical penetration). As indicated by CHANCE (column 3, lines 20-33) the stimulus need NOT be magnetic (as necessitated in the present case) but an electric field can be also be used for the sole purpose of providing stimulus

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for imaging brain activity in the stimulated area (column 6, line 33, column 9, lines 37-51). CHANCE's optical tomography system is analogous to an MRI imaging method, where the magnet (generally at a fixed frequency) is used to manipulate nuclear spins. Conversely, in the present case, the change in magnetic field is used to manipulate electronic spins, which are excited by photons to various electronic states, to produce different chemical pathways for the PDT drug effect.

In the present invention, the variation in the magnetic field is used to select a reaction pathway of the PDT agent and not to construct an image in the presence of a changing magnetic stimuli (CHANCE, column 3 lines 20-33). The addition of LILGE's fiber optic for general sensing of fluorephore/phosphore emission of photoactive groups does not change the argument that the magnet must be used with the objective to alter the drug chemistry by modifying electronic spin states. Furthermore, the present invention states that not all photosensitizers are subject to the magnetic field-chemical change, specifying metallophthalocyanines as potential candidates based on their unique radical chemistry and mechanisms and which is not typically accessed in PDT treatment. While the present application does have some common optical sensing components typically used to acquire optical data for PDT treatment monitoring/dosimetry (LILGE abstract), the instrument of the invention is rather a manipulation of the drug's chemistry, and measuring the corresponding optical emission in an optical domain.

The Applicant agrees that LILGE describes a multi-tasking optical probe with various sensor zones of temporal or spatial emissions of phosphorescence and fluorescence (column 3, line 1-10, column 5, 57-60). LILGE also states that the excitation wavelength may or may not need to be matched to that of the treatment wavelength. While present claims 10 and 11 suggest either the same source or different wavelength sources for inducing PDT drug toxicity (therapeutic application of this magneto-optical device), this is not a crucial point to the invention. Rather, claims 10 and 11 are intended to permit a variability of choice and design of photosensitizer drug with appropriate magnetic susceptibility in order to induce the magneto-

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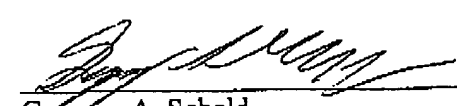
linked phototoxicity via a different pathway (i.e. without restriction to the drug's therapeutic application to solely its excitation wavelength).

It is respectfully submitted that the amended claims patentably distinguish over the prior art of record and Applicant requests that the rejections be withdrawn. Applicant asserts that the application is in condition for allowance and that a notice to that effect is earnestly solicited.

If the Examiner feels that a telephone interview may be helpful in this matter, please contact Applicant's representative at 612.336.4728.

Respectfully submitted,

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